Kaneka Pharma America LLC
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510(k) Summary

DEC 17 2012

a. Owner/Company name, address

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b. Contact

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c. Application Correspondent

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d. Date prepared

March 23, 2012

e. Name of device

Trade Name:	LACRIFLOW
Common Name:	Lacrimal stent
Classification Name:	Lacrimal Stents and Intubation Sets
Classification Regulation:	Unclassified
Product Code:	OKS

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f. Predicate devices

The LACRIFAST is substantially equivalent to the following legally marketed devices:

510(k):	K991238
Trade name:	FCI CRAWFORD PROBE INTUBATION SETS
Product code:	OKS

510(k):	K041869
Trade name:	SELF RETAINING BICANALICULUS INTUBATION SET
Product code:	OKS

g. Description of the device

The LACRIFLOW is intended for the treatment of epiphora due to conditions including the obstructions of lacrimal punctum, lacrimal canaliculus, or nasolacrimal duct. The LACRIFLOW consists of the Lacrimal duct tube and the Bougie. The Lacrimal duct tube is intended to be inserted and placed inside the lacrimal canaliculus or other sites to dilate the lacrimal duct, and the Bougie is intended to be used for the insertion of the Lacrimal duct tube and removed after insertion of Lacrimal duct tube. Lacrimal duct is dilated by insertion of the Lacrimal duct tube into the obstructed site.

h. Indications for Use

Indications for Use

The LACRIFLOW is indicated in treatments of epiphora in-patients 12 months and older, in cases of:

- Canalicular pathologies (stenosis, obstruction, lacerations),
- During Dacryocystorhinostomy (conventional or laser),
- Congenital nasolacrimal duct obstruction.

i. Statement of substantial equivalence

Following table is comparison between the LACRIFLOW and the predicates.

The Indications for Use of the LACRIFLOW is similar to that of the FCI CRAWFORD PROBE INTUBATION SETS (K991238). The elastic tube is inserted and placed inside the lacrimal drainage system in the application of the LACRIFLOW and the predicates, and thus the fundamental technology of the LACRIFLOW and the predicate is same.

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	LACRIFLOW	FCI CRAWFORD PROBE INTUBATION SETS (K991238)	SELF RETAINING BICANALICULUS INTUBATION SET (K041869)
Indications for Use	The LACRIFLOW is indicated in treatments of epiphora in patients 12 months and older, in cases of: -Canalicular pathologies (stenosis, obstruction, lacerations), -During Dacryocystorhinostomy (conventional or laser), -Congenital nasolacrimal duct obstruction.	BICANALICULAR INTUBATION SETS are indicated in treatments of epiphora in infants or adults, particularly in cases of: -Canalicular pathologies (stenosis, obstruction, lacerations), -Dacryocystorhinostomy (conventional or laser), -Imperforation of the nasolacrimal duct in the infant.	Bicanalicular intubation is indicated in treatments of epiphora in adults (not to be used in infants), particularly in cases of: -Meatic pathologies (meatic atresia) -Canalicular pathologies (canalicular stricture).
Tube Material	Polyurethane resin	Silicone	Silicone
Tube Shape	Two tubes are connected by a rod part	One tube	Two tubes are connected by a rod part
Size of the Tube			
- Length	Standard type: 105 mm Short type: 90 mm Mini type: 50 mm	Mini: 309.7mm Maxi: 311.15mm	S1-1290u: 25mm S1-1291u: 30mm S1-1292u: 35mm
-Outer Diameter	Tube part: 1.0 mm Rod part: 0.7 mm	0.64 mm	0.64 mm
Tensile Strength of the Tube	14.2 N (Average of 9 samples)	3.56 N (Average of 3 samples)	1.98N (Average of 3 samples)
Insertion Method	The LACRIFLOW consists of the tube and the Bougie, and thus the Bougie is used for insertion.	BICANALICULAR INTUBATION SETS are composed of a tube connected to a steel guide at each end, and thus the steel guide is used for insertion.	The tube has flexible silicone anchor-shaped heads, and thus a forceps is used for insertion.
Insertion Assist Parts	The Bougie	The steel guides at both ends	NA (assisted by a forceps)
-Length	55 mm	Mini: 108 mm Maxi: 115 mm	NA
-Outer Diameter	0.5 mm	0.38 mm	NA
-Tip Shape	Straight, helically grooved	Rounded olive shape	NA
-Tip Diameter	The same as the outer	Mini: 0.75 mm	NA

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	diameter	Maxi: 1.01 mm	
-Material	Stainless steel	Stainless steel	NA
Sterilization	Yes (Ethylene Oxide)	Yes (Ethylene Oxide)	Yes (Ethylene Oxide)
Single-Use Only	Yes	Yes	Yes

As shown in the comparison table, the indications for use of the LACRIFLOW is similar to the FCI CRAWFORD PROBE INTUBATION SETS (K991238). In addition, as described above, the fundamental technology that the elastic tube is inserted and placed inside the lacrimal drainage system of the LACRIFLOW and the predicate is same. In the comparison table, there are some differences in characteristics between the LACRIFLOW and the predicates including the FCI CRAWFORD PROBE INTUBATION SETS (K991238) and the SELF RETAINING BICANALICULUS INTUBATION SET (K041869). Regarding the LACRIFLOW and the FCI CRAWFORD PROBE INTUBATION SETS (K991238), the tube shape and tube length are different because of difference of final step before the implantation. The FCI CRAWFORD PROBE INTUBATION SETS (K991238) needs to be tied both end, however, the LACRIFLOW does not need that step because the tube part is thicker than the lacrimal canaliculus. Regarding the LACRIFLOW and the SELF RETAINING BICANALICULUS INTUBATION SET (K041869), the tube length is different because the SELF RETAINING BICANALICULUS INTUBATION SET (K041869) is intended to be implanted in lacrimal canaliculus, not in nasolaclimal duct. In addition, the material of the Tube and insertion method including insertion assist part of the LACRIFLOW are different from the predicates. Therefore, performance testing, sterilization validation, biocompatibility testing, and risk analysis were performed in order to evaluate safety and effectiveness of the LACRIFLOW. In conclusion, those testing and analysis demonstrated that the LACRIFLOW did not raise any new safety or effectiveness concerns.

j. Risk Analysis

The LACRIFLOW was evaluated in accordance with ISO14971:2007. The risk management of the device was deemed satisfactory.

k. Bench Testing

The following bench tests were performed to ensure the safety and effectiveness of the Lacriflow and the conformance to in-house standards, and compare the characteristics with the predicate.

- Tensile Strength of the Lacrimal duct tube
  The tensile strength of the Lacrimal duct tube met acceptable minimum force until breakage when tested according to in-house standard.

- Stiffness of the Bougie
  The stiffness of the Bougie met acceptance criteria when tested according to in-house standard.

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Result of the all performance tests showed that the LACRIFLOW was compliant with in-house standards and the test result did not raise any new safety and effectiveness concern.

l. Biocompatibility Testing

In order to evaluate biocompatibility for the LACRIFLOW, we performed following biocompatibility tests;

- Cytotoxicity
- Irritation
- Sensitization
- Acute Systemic Toxicity
- 4-week and 13-week Systemic Toxicity
- Implantation (2-week and 9-week)
- Genotoxicity
- Hemolysis
- Pyrogen test
- LAL test

In the biocompatibility testing reports, no biocompatibility concern was raised.

m. Conclusion

The LACRIFLOW has the similar intended use to the FCI CRAWFORD PROBE INTUBATION SETS (K991238). The elastic tube is inserted and placed inside the lacrimal canaliculus in the application of the LACRIFLOW and the predicates, and thus the fundamental technology of the LACRIFLOW and the predicate is same. Although the LACRIFLOW has some different characteristics from the predicates including the FCI CRAWFORD PROBE INTUBATION SETS (K991238) and the SELF RETAINING BICANALICULUS INTUBATION SET (K041869), the LACRIFLOW did not raise any new safety or effectiveness concerns as the results of performance testing, sterilization validation, biocompatibility testing and risk analysis. Based on such testing and analysis, we concluded that the LACRIFLOW is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 17, 2012

Kaneka Pharma America LLC
c/o Fumiaki Kanai, Ph.D.
President and CEO, MIC International
4-1-17 Hongo
Bunkyo-ku, Tokyo, 13-0033, Japan

Re: K120886
Trade/Device Name: LACRIFLOW Lacrimal Stent
Regulation Number: None
Regulation Name: Lacrimal Stents and Intubation Sets
Regulatory Class: Unclassified
Product Code: OKS
Dated: November 9, 2012
Received: November 13, 2012

Dear Dr. Kanai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (If known): K120886

Device Name: LACRIFLOW

Indications for Use

The LACRIFLOW is indicated in treatments of epiphora in patients 12 months and older, in cases of:

- Canalicular pathologies (stenosis, obstruction, lacerations),
- During Dacryocystorhinostomy (conventional or laser),
- Congenital nasolacrimal duct obstruction.

X

Prescription Use _____ AND/OR Over-the Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Neurological and Physical Medicine Devices
510(k) Number K120886